



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to the raw fruit of *Emblica officinalis* Gaertn. and maintenance of normal blood LDL-cholesterol concentrations (ID 4041) and protection of DNA, proteins and lipids from oxidative damage (ID 4042) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to the raw fruit of *Emblica officinalis* Gaertn. and maintenance of normal blood LDL-cholesterol concentrations (ID 4041) and protection of DNA, proteins and lipids from oxidative damage (ID 4042) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to the raw fruit of *Emblica officinalis* Gaertn. and maintenance of normal blood LDL-cholesterol concentrations and protection of DNA, proteins and lipids from oxidative damage. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food that is the subject of the health claims is “*Emblica officinalis* fruit rind”. From the references provided the Panel considers that the raw fruit of *Emblica officinalis* Gaertn. is sufficiently characterised in relation to the claimed effects.

Maintenance of normal blood LDL-cholesterol concentrations

The claimed effect is “cardiovascular”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance of normal blood LDL-cholesterol concentrations. The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

¹ On request from the European Commission, Question No EFSA-Q-2008-4753, EFSA-Q-2008-4754, adopted on 08 April 2011.

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No human studies were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the raw fruit of *Emblica officinalis* Gaertn. and maintenance of normal blood LDL-cholesterol concentrations.

Protection of DNA, proteins and lipids from oxidative damage

The claimed effect is “antioxidant; immunity”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the protection of DNA, proteins and lipids from oxidative damage. The Panel considers that protection of DNA, proteins and lipids from oxidative damage may be a beneficial physiological effect.

No human studies were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the raw fruit of *Emblica officinalis* Gaertn. and protection of DNA, proteins and lipids from oxidative damage.

KEY WORDS

Emblica officinalis Gaertn., LDL-cholesterol, oxidative damage, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out⁵. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claims is “*Emblica officinalis* fruit rind”.

Emblica officinalis Gaertn. (synonym of the species *Phyllanthus emblica* L., also known as Indian gooseberry) is a tree of the *Phyllanthaceae* family (genus *Phyllanthus*) and it is known for its edible, round, light green fruits of the same name. The proposed conditions of use refer to powder and aqueous extract (ID 4041, 4042) and to raw fruit and raw fruit extract (ID 4041). The Panel notes that no information on the composition or manufacturing process of the powder and aqueous extract, or of the raw fruit extract, has been provided. However, the Panel notes that, from the references provided (Jacob et al., 1988), the raw fruit of *Emblica officinalis* Gaertn. can be characterised for its content of ascorbic acid, pectins, tannins and fibre in relation to the claimed effects.

The Panel considers that the food, the raw fruit of *Emblica officinalis* Gaertn., which is the subject of the health claims, is sufficiently characterised in relation to the claimed effects.

2. Relevance of the claimed effect to human health

2.1. Maintenance of normal blood LDL-cholesterol concentrations (ID 4041)

The claimed effect is “cardiovascular”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance of normal blood LDL-cholesterol concentrations.

Low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention >160 mg/dL (>4.14 mmol/L), may compromise the normal structure and function of the arteries.

The Panel considers that maintenance of normal blood cholesterol concentrations is a beneficial physiological effect.

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

⁵ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

2.2. Protection of DNA, proteins and lipids from oxidative damage (ID 4042)

The claimed effect is “antioxidant, immunity”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the protection of DNA, proteins and lipids from oxidative damage.

The Panel considers that claims made on the antioxidant capacity/content of foods based on their capability of scavenging free radicals *in vitro* refer to a property of the food/food constituent measured in model systems, and that the information provided does not establish that this exerts a beneficial physiological effect in humans as required by Regulation (EC) No 1924/2006.

Reactive oxygen species (ROS) including several kinds of radicals are generated in biochemical processes (e.g. respiratory chain) and as a consequence of exposure to exogenous factors (e.g. radiation, pollutants). These reactive intermediates damage molecules such as DNA, proteins and lipids if they are not intercepted by the antioxidant network which includes free radical scavengers such as antioxidant nutrients.

The Panel considers that protection of DNA, proteins and lipids from oxidative damage may be a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Maintenance of normal blood LDL-cholesterol concentrations (ID 4041)

Among the references provided were a number of textbooks and monographs which did not provide any original data for the scientific substantiation of the claim. One narrative review on antioxidant properties was not related to the claimed effect. A number of references provided were in Japanese and the translation into a EU language was not available to the Panel. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One reference reported on an uncontrolled human intervention study which investigated the effect of 50 g of the raw fruit *Emblica officinalis* Gaertn. consumed for four weeks on total, HDL- and LDL-blood cholesterol concentrations in 20 hypercholesterolaemic and 15 normocholesterolaemic subjects (Jacob et al., 1988). The Panel notes that this study was uncontrolled and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no human studies have been provided from which conclusions can be drawn for the scientific substantiation of the claim. The Panel considers that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of *Emblica officinalis* Gaertn. consumption on maintenance of normal blood LDL-cholesterol concentrations *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the raw fruit of *Emblica officinalis* Gaertn. and maintenance of normal blood cholesterol concentrations.

3.2. Protection of DNA, proteins and lipids from oxidative damage (ID 4042)

Among the references provided for the scientific substantiation of the claim were two references which were not accessible to the Panel even after every reasonable effort had been made to retrieve them, and a number of textbooks which did not include any original data for the scientific

substantiation of the claim. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

The Panel notes that no human studies which addressed outcomes related to the claimed effect have been provided. The Panel considers that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of *Emblica officinalis* Gaertn. consumption on protection of DNA, proteins and lipids from oxidative damage *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the raw fruit of *Emblica officinalis* Gaertn. and protection of DNA, proteins and lipids from oxidative damage.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, the raw fruit of *Emblica officinalis* Gaertn., which is the subject of the health claims, is sufficiently characterised in relation to the claimed effects.

Maintenance of normal blood LDL-cholesterol concentrations (ID 4041)

- The claimed effect is “cardiovascular”. The target population is assumed to be the general population. Maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of the raw fruit of *Emblica officinalis* Gaertn. and maintenance of normal blood LDL-cholesterol concentrations.

Protection of DNA, proteins and lipids from oxidative damage (ID 4042)

- The claimed effect is “antioxidant, immunity”. The target population is assumed to be the general population. Protection of DNA, proteins and lipids from oxidative damage may be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of the raw fruit of *Emblica officinalis* Gaertn. and protection of DNA, proteins and lipids from oxidative damage.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q- 2008-4753, EFSA-Q-2008-4754). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

REFERENCES

Jacob A, Pandey M, Kapoor S and Saroja R, 1988. Effect of the Indian gooseberry (amla) on serum cholesterol levels in men aged 35-55 years. *European Journal of Clinical Nutrition*, 42, 939-944.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁶ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁷

Foods are commonly involved in many different functions⁸ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

⁶ OJ L12, 18/01/2007

⁷ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁸ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps

maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.

- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to the raw fruit of *Emblica officinalis* Gaertn., including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
4041	Emblica officinalis FRUIT RIND	Cardiovascular	Supports heart function and blood quality. Contributes to normal cholesterol. Contributes to the health of the cardiovascular system
	Conditions of use <ul style="list-style-type: none"> - Powder 3-0.2 g/day; aqueous extra 1.5-0.1 g/day. All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose - 50g of raw fruit /day of 400-800mg /day of fruit extracts - 50 mg/kg bw in animal studies 		
ID	Food or Food constituent	Health Relationship	Proposed wording
4042	Emblica officinalis FRUIT RIND	Antioxidant. Immunity	<p>Strengthens the immune system. Strengthens the body's natural defenses.</p> <p>-Strengthens the body's natural defenses. Helps maintain the immune system, the body's natural defenses. Contains a high amount of naturally occurring antioxidants</p> <p>-Antioxidants help protect you from radicals which cause cell damage/antioxidants help protect your cells, tissues and organs from oxidative damage</p> <p>Antioxidants contribute to the total antioxidant capacity of the body and may help strengthen your body's defences. Helps protect your body's cells, tissues and organs.</p>
	Conditions of use <ul style="list-style-type: none"> - Powder 3-0.2 g/day; aqueous extra 1.5-0.1 g/day. All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose 		

GLOSSARY AND ABBREVIATIONS

DNA	Deoxyribonucleic acid
HDL	High-density lipoproteins
LDL	Low-density lipoproteins
ROS	Reactive oxygen species